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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/084,160 | 02/28/2002 | Shuji Kaneko | 220125US0 X | 4862 |

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| EXAMINER |
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JONES, DWAYNE C

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/084,160

Applicant(s)

KANEKO ET AL.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on the election of 19 MAY 03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2 and 10-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-20 are pending.
2. Claims 3-8 are elected and rejected.
3. Claims 1, 2, and 9-20 are nonelected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election with traverse of Group II, corresponding to claims 3-8, in Paper No. 7 is acknowledged. In addition, applicants have elected the species of dementia for the brain disorder. The traversal is on the ground(s) that the three Groups are related. This is not found persuasive because these Groups do have different functions and modes of operation. In particular, the method of screening of Group III would require a different field of search than a method of treating a brain disorder of Group II as well as methods of potentiating a N-type Ca^{2+} channel activity, which is directed in the field of electrophysical biochemistry and membrane conductance.
5. The requirement is still deemed proper and is therefore made FINAL.
6. This application contains claims 1-2 and 9-14 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

7. The information disclosure statement filed on October 17, 2002 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to, "prophylaxis or treatment of brain disorders" with the instantly claimed compounds. The claimed methods of treatment, not to mention prophylaxis, fail to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. 112, first paragraph. There is insufficient descriptive support for the generic limitation, "prophylaxis or treatment of brain disorders" as well as the litany of diseases listed in claims 4 and 6 with the instantly claimed compounds. Furthermore, the claimed methods require treatment of unspecified diseases and there is no evidence in the instant specification, which supports these claims. In the absence of some

Art Unit: 1614

understanding of the conditions to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed methods.

10. Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the phrase "a compound having an effect of specifically potentiating an N-type Ca^{2+} channel activity". In addition, the instant specification does not describe what is meant by the term/phrase "a compound having an effect of specifically potentiating an N-type Ca^{2+} channel activity" other than the compounds of formula (I). Structural identifying characteristics of the phrase "a compound having an effect of specifically potentiating an N-type Ca^{2+} channel activity" are not disclosed except for those compounds of formula (I). There is no evidence that there is any per se structure/function relationship between the phrase "a compound having an effect of specifically potentiating an N-type Ca^{2+} channel activity" other than those disclosed, namely the compounds of formula (I). The instant specification does provide an adequate written description for the phrase of "a compound having an effect of specifically potentiating an N-type Ca^{2+} channel activity". Accordingly, these claims fail to comply with the written description requirement.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1614

12. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to the meaning of the group, "ar(lower)alkoxy". In particular, it is unclear as to the meaning of the variable of "ar" as opposed to - aryl -. Consequently, these claims are rendered vague and indefinite.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 3-6 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Wang et al. Wang et al. teach of the administration of the anti-dementia drug of FK 960. This compound is shown to ameliorate the memory deficits in various experimental models of dementia. In addition, this compound is shown to have an effect of the voltage-activated Ca^{2+} channels, (see abstract).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. Wang et al. teach of the administration of the anti-dementia drug of FK 960. This compounds is shown to ameliorate the memory deficits in various experimental models of dementia. In addition, this compound is shown to have an effect of the voltage-activated Ca^{2+} channels, (see abstract). Although Wang et al. do not specifically recite the monohydrate salt of the instantly claimed compounds of FF906, the prior art reference of Wang et al. do teach of the very same compound that is claimed in this invention. It is well within the purview of the skilled artisan to select

Art Unit: 1614

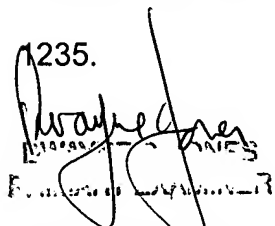
pharmaceutically acceptable salts, namely the monohydrate of a compound. It would have been obvious in view of Wang et al. for the skilled artisan to determine the pharmaceutically acceptable salt, such as the monohydrate of FK906, for the treatment against dementia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

A handwritten signature in black ink, appearing to read "D. C. Jones", is written over a faint, rectangular stamp. The stamp contains some illegible text, possibly a date or reference number.

Tech. Ctr. 1614

July 25, 2003